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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/610,838	07/06/00	BETTER	M 11022US11/20

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EXAMINER

SALIMI, A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

009020" 8880T960

Office Action Summary

Application No.
09/610,838

Applicant(s)
Better et al

Examiner
ALI R. SALIMI

Group Art Unit
1648



☒ Responsive to communication(s) filed on 11/3/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1648

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

Claims 1-17 are pending.

Acknowledgment is made of the letter dated 11/3/2000 requesting the transfer of Sequences from the parent application serial no. 09/136,389 into the current application.

Priority

Applicant's claim for 119 benefit to PCT/US92/09487 (November 4, 1992) is noted; however, benefit is denied, since said application was filed more than one year before PCT international application PCT/US94/05348. It is further noted that there is no 119 notation printed on the face of the patents 5,376,546, and 5,416,202; these patents are derived from parent applications 07/901,707 and 07/988,430. Moreover, PCT/US94/05348 (WO 94/26910) does not refer to the PCT/US92/09487 in its priority reference in any manner. In addition the MPEP(1893.03(c)) indicates that "For a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 120 of a prior U.S. national application, the international

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application ("X") must include an appropriate reference to the prior U.S. national application, be copending with the prior U.S. national application, and have at least one inventor in common with the prior U.S. national application, MPEP § 201.11. The prior U.S. national application is copending with the national stage application if the prior U.S. national application was pending on the international filing date."

Claim Rejections - 35 USC § 112

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite since the metes and bounds of the gelonin protein is not clear. In addition, the metes and bounds of the targeting sequence that allows internalization is not defined. The claim is further rejected because the antibody specificity has not been defined.

What are the antigen binding portions of antibody, a hormone, a lymphokine or a growth factor? Is this antibody specific for all the cell surface receptors? Claims 2-17 are rejected because they are dependent from claim 1.

Claim 4 is vague and indefinite, the intended linker is not defined. The term "capable of" in claim 4 is confusing. The term "capable of" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art

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would not be reasonably apprised of the scope of the invention. In the instant case, the definition of "capable of" has many meaning, therefore, the claim is considered as indefinite. Does the binding take place or not?

Claim 6 is unclear, the metes and bounds of the antibody is not defined. What kind of antibody is intended. Is IgM intended?

Claim 7 is confusing and indefinite for their recitation of " an antigen binding portion of an antibody", are every subclass of antibodies intended? What are the portion or portions? This affects the dependent claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-17 are rejected under the judicially created doctrine of double patenting over disclosure of U. S. Patent No. 5,837,491 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The Sequence ID No: 2 is fully disclosed.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-17 are rejected under the judicially created doctrine of double patenting over disclosure of U. S. Patent No. 6,146,850 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The Sequence ID No: 2 is fully disclosed.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application

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which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

See also MPEP § 804.

Claims 1-17 are rejected under the judicially created doctrine of double patenting over disclosure and claims of U. S. Patent No. 6,146,631 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The Sequence ID No: 2, and 101, plus the linkers are fully disclosed.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-17 are rejected under the judicially created doctrine of double patenting over disclosure and claims of U. S. Patent No. 5,756,699 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The Sequence ID No: 2, and 101, plus the linkers are fully disclosed.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application

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which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

See also MPEP § 804.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

3/1/2001

AKS
ALI R. SALIMI
PRIMARY EXAMINER